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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/579,137	05/15/2006	Jussi Nurmi	TUR-181	3667

32954 7590 09/16/2011

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ART UNIT	PAPER NUMBER
1637	

MAIL DATE	DELIVERY MODE
09/16/2011	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/579,137
Filing Date: May 15, 2006
Appellant(s): NURMI ET AL.

James C. Lydon
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed June 29, 2011 appealing from the Office action mailed October 12, 2010.

(1) Real Party in Interest

The examiner has no comment on the statement, or lack of statement, identifying by name the real party in interest in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The following is a list of claims that are rejected and pending in the application:

Claims 18-19 and 21-30 are pending and rejected. Claims 1-17 and 20 have been cancelled.

(4) Status of Amendments After Final

The examiner has no comment on the appellant's statement of the status of amendments after final rejection contained in the brief.

(5) Summary of Claimed Subject Matter

The examiner has no comment on the summary of claimed subject matter contained in the brief.

(6) Grounds of Rejection to be Reviewed on Appeal

The examiner has no comment on the appellant's statement of the grounds of rejection to be reviewed on appeal. Every ground of rejection set forth in the Office action from which the appeal is taken (as modified by any advisory actions) is being maintained by the examiner except

for the grounds of rejection (if any) listed under the subheading "WITHDRAWN REJECTIONS." New grounds of rejection (if any) are provided under the subheading "NEW GROUNDS OF REJECTION."

(7) Claims Appendix

The examiner has no comment on the copy of the appealed claims contained in the Appendix to the appellant's brief.

(8) Evidence Relied Upon

2004/0229349	DARIDON	11-2004

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 18-19 and 21-30 are rejected under 35 U.S.C. 102(e) as being anticipated by Daridon et al. (US PgPub 2004/0229349; 102(e) date, April 1, 2002). Daridon teaches a filtration and sorting apparatus useful for detection of cellular materials (Abstract).

With regard to claim 18, Daridon teaches an assay for quantitative and/or qualitative analysis of the presence of a specific analyte or specific analytes in a biological sample, which analytes, if present, are contained in biological particles of said sample, said assay comprising forcing said sample in a first direction through a filter that retains said biological particles (Fig 17 and 18, p. 30, paragraph 443-449, 622 is the filter and is designed to pass fluid readily, but will retain particles and may be size selective, see [446] and [449], where particle 620 is retained), removing biological particles from said filter by a flush flow in a second direction opposite said first direction, and analyzing biological particles contained in said flush flow (p. 30, [449] where particle is displaced by fluid flowing in reverse across filter channel and repositioned to analysis site 632), and analyzing biological particles contained in said flush flow by means of a nucleic acid amplification assay (paragraph 246, 288, 307, where the retained particle or cell can be analyzed by PCR amplification), wherein said flush flow is analysed for the analyte or analytes without any further purification (p. 30, [449] where the repositioned particle is moved to an analysis site without further purification).

With regard to claim 19, Daridon teaches an embodiment of claim 1, further comprising performing an initial filtration which does not retain the biological particles containing the analyte or analytes but retains particles that might interfere with the analysis of the analyte or analytes, said initial filtration being performed prior to forcing said sample in a first direction through a filter which retains said biological particles (Embodiment 4, [538] where the system flushes fluid through the chamber to prevent clogging of the filter).

With regard to claim 21, Daridon teaches an embodiment of claim 1, wherein retention of the biological particles containing the analyte or analytes in the filter is dependent on the size of

the particles (p. 30, [446] where "in some embodiments, the diameter of filter channel 616 allows size-selective retention of a single particle").

With regard to claim 22, Daridon teaches an embodiment of claim 1 wherein retention of the biological particles containing the analyte or analytes in the filter is essentially dependent on the chemical properties of the particle (p. 14 [253] where the particle is retained based on a chemical interaction).

With regard to claim 23, Daridon teaches an embodiment of claim 18, wherein the biological particles containing the analyte or analytes are selected from the group consisting of prokaryotic or eukaryotic cells or spores or components thereof, viruses or viral particles, complexes comprising protein and/or nucleic acid, and any combination thereof (p. 7-8, [149-164], where the particles or analytes include biological cells including eukaryotic and prokaryotic cells and viruses).

With regard to claim 24, Daridon teaches an embodiment of claim 6, wherein the biological particles containing the analyte or analytes are selected from the group consisting of bacteria, bacterial cell, plant pollen, mitochondria, chloroplast, cell nuclei, virus, phage, chromosome and ribosome (p. 7-8, [149-164], where the particles or analytes include biological cells including eukaryotic and prokaryotic cells and viruses).

With regard to claim 25, Daridon teaches an embodiment of claim 1, wherein the means of analysing the analyte or analytes is selected from the group consisting of polymerase chain reaction (PCR), reverse transcriptase polymerase chain reaction (RT-PCR), ligase chain reaction (LCR), proximity ligation assay, nucleic acid sequence based amplification (NASBA),

strand displacement amplification (SDA) and any combination thereof (p. 14, [246], where the types of analysis include PCR).

With regard to claim 26, Davidon teaches an embodiment of claim 1, wherein said flush flow comprises a liquid or gas not contained in said sample (p. 9, [177] where positioning or facilitation mechanisms can include external liquid or gas pressure).

With regard to claim 27, Daridon teaches an embodiment of claim 1 wherein the analyte or analytes are selected from the group consisting of a living and/or dead cell or virus; a peptide, a protein or complex thereof; a nucleic acid; and any combination thereof (p. 7-8, [149-164], where the particles or analytes include biological cells including eukaryotic and prokaryotic cells and viruses).

With regard to claim 28, Daridon teaches an embodiment of claim 10, wherein the analyte or analytes comprises living and/or dead cells and/or viruses selected from the group consisting of a mold, a yeast, a eukaryotic cell or organism, a pathogenic virus and a cancer cell (p. 7-8, [149-164], where the particles or analytes include biological cells including eukaryotic and prokaryotic cells and viruses).

With regard to claim 29, Daridon teaches an embodiment of claim 10, wherein the analyte or analytes comprises nucleic acids selected from the group consisting of DNA, RNA and any derivative thereof (p. 12-13, [223] where the nucleic acids can include DNA or RNA).

With regard to claim 30, Daridon teaches an embodiment of claim 10, wherein the analyte or analytes comprises peptides and/or proteins or complexes thereof selected from the group consisting of a hormone, a growth factor, an enzyme or parts thereof and/or complexes

thereof; and any combination thereof (p. 14, [248] where the characteristic detected in the analyte includes nucleic acids, proteins, enzymes and a variety of additional factors).

(10) Response to Argument –

Appellant traverses the rejection of claims as being anticipated by Daridon. Applicant argues "Daridon fails to disclose performing a nucleic acid amplification assay on a reverse flush flow without purification" (p. 5 of brief). Appellant emphasizes that "Daridon does not expressly disclose its reverse flush flow should be analyzed without purification". Appellant argues the "affirmative 'no purification' requirement is nowhere disclosed in Daridon". Appellant references a portion of paragraph 449 and argues "'repositioning' does not require that no purification of the flush flow occur prior to analysis" and that "[t]here is no disclosure, one way or other" regarding the potential for purification of the flush flow. Appellant also argues that one of ordinary skill would not interpret the passage as requiring analysis of the flush flow without purification (p. 6-7 of brief). Appellant concludes that "Daridon does not inherently disclose its reverse flush flow should be analyzed without purification" (p. 8 of brief).

These arguments have been considered, but are not persuasive. Appellant's argument that the lack of positive recitation that purification does not occur would not suggest to one of ordinary skill in the art that purification must occur. As noted by Carl Sagan "The absence of evidence is not evidence of absence". While Daridon does not specifically state that purification does not occur, Daridon also does not state that purification occurs. One cannot assume that purification must occur simply because it is not specifically mentioned that it should be avoided. Appellant's speculation of the potential need for purification is not a sound basis for overcoming the rejection in view of Daridon. To the contrary, one of ordinary skill would assume that if

purification was intended to be included, it would have been mentioned. Further, as noted in the rejection the Daridon reference indicates direct transfer of the sample from one site to another, which does not in any way suggest that purification steps are intended and not recited. To assume that it does, based only on mere speculation of movement of the sample is not persuasive. Therefore, Appellant's arguments in this regard are not persuasive.

Next, Appellant argues that "Daridon does not arrange or combine its particle retention, reverse flush flow, and nucleic acid amplification disclosures in the same way as the limitations of the claimed assay" (p. 9 of brief). Appellant argues this point from the position that Daridon discloses a large number of microfluidic particle analysis systems and that they "may be combined in any suitable order and/or employed for any suitable number of times within a system" (p. 10-12 of brief). Appellant summarizes the teachings at each citation of Daridon noted in the rejection (p. 13-14 of brief). Appellant goes on to argue that the reverse flow particle capture is "unrelated to its nucleic acid amplification assay disclosure" (p. 15 of brief). Appellant cites again to paragraph 449 and argues "paragraph 449 does not disclose whether its analysis site 632 is adapted to perform a nucleic acid amplification assay" (p. 17 of brief). Applicant goes on to argue that "none of the examples use a microfluidic particle system with nucleic acid amplification" and then notes that "Daridon merely discloses that PCR is one of several detection methods which can be used in conjunction with its microfluidic systems" (p. 18 of brief). Applicant concludes that the rejection combines isolated disclosures that are unrelated to construct the rejection.

These arguments have been considered, but are wholly unpersuasive. As noted throughout Appellant's arguments, paragraph 449 teaches the claimed invention including the process of forcing a sample through a filter to retain biological particles, removing biological particles by flush flow in the opposite direction and analyzing the biological particles and where the analysis is carried out on the flush flow. While paragraph 449 generally refers to an analysis site, where further analysis is necessarily carried out, and does not make specific mention of amplification, thuis does not mean that the rejection combines "isolated disclosures" that are "unrelated." To the contrary, each of the cited paragraphs which reference amplification refer specifically that they are useful in microfluidic systems. In particular, paragraph 307, refers to single cell assays carried out in microfluidic systems that require "retention of a single cell" and the microfluidic system of Figure 18 is necessarily one of these systems. Therefore, it is clear that these disclosures are not unrelated. To the contrary, these disclosures are specifically related. Furthermore, paragraph 307 entitled "Single Cell Assays" is directly followed by "Sorting/Selection" (see paragraph 309-310) which provides another connection between these disclosures of Daridon with the specific embodiment described in paragraph 449, since this passage is specifically aimed towards sorting and selection, which is achieved in Figure 18 (paragraph 449) through control of the flow and capture of the biological particle (e.g., cell). Therefore, Applicant's arguments are not persuasive and the rejection is maintained.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/STEPHANIE K MUMMERT/

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/Gary Benzion/
Supervisory Patent Examiner, Art Unit 1637

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